

### **REMARKS**

Claims 16-32 are currently pending in this application. In the Office Action mailed on January 12, 2005 ("Office Action"), claims 1-15 were withdrawn from consideration pursuant to a provisional election without traverse of the invention of claims 16-20 made during a telephone conversation with Attorney Jonathan Spangler on December 8, 2004. Claims 16-20 were rejected. Through this amendment, Applicants have cancelled claims 1-15 without prejudice, claim 16 has been amended, and new claims 21-38 have been added. No new matter has been entered. Applicants respectfully request favorable consideration of the present application in light of the amendments to the claims and the following remarks.

#### **I. Election**

In paragraph 1 of the Office Action, a Restriction Requirement was set forth calling for an election between Invention I (claims 1-15) and Invention II (claims 16-20). Further to the provisional election referenced in Paragraph 2 of the Office Action, Applicants hereby affirm the provisional election of Invention II (claims 16-20) for prosecution on the merits. As part of this election, claims 1-15 have been cancelled from prosecution, without prejudice.

#### **II. Claim Rejections – 35 USC § 103(a)**

##### **A. Mannschedel in view of Shoher et al.**

Claims 16, 19 & 20 were rejected by the Examiner under 35 USC 103(a) as being unpatentable over US Patent No. 6,126,446 to Mannschedel ("Mannschedel") in view of US Patent No. 5,272,184 to Shoher et al ("Shoher"). Applicants respectfully traverse this rejection as set forth below.

To establish a *prima facie* case of obviousness under 35 USC § 103(a) in view of a reference or combination of references, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Third, the prior art reference(s) must teach or suggest all the claim limitations. Obviousness can only be established

by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either explicitly or implicitly in the references themselves or in the knowledge generally available to one of ordinary skill in the art. Finally, in determining the differences between the prior art and the claims, the question under 35 USC § 103 is not whether the differences themselves would have been obvious, but whether the claimed invention as a whole would have been obvious.

Independent claim 16 discloses a method of preparing a thermopolymer composition for use in surgery, comprising the steps of: (a) selecting a thermopolymer matrix from a group consisting of gutta percha, balata and polyisoprene, or any mixture thereof; (b) selecting a dispersion compound comprising at least one of titanium and gold; (c) combining the thermopolymer matrix and the dispersion compound to form a thermopolymer composition; and (d) sterilizing said thermopolymer composition.

Neither the Mannschedel nor Shoher references, alone or in combination, appear to disclose or suggest all of the features of amended Claim 16. Among other voids, these references appear to be completely silent regarding preparing a thermopolymer composition *for use in surgery*, and the essential claimed step of “*sterilizing said thermopolymer composition.*” Mannschedel discloses a composition for filling tooth root canals comprising an isoprene-based powder and a sealer (abstract). Shoher discloses a metal composite for filling a dental cavity (abstract). That both the Mannschedel and Shoher references concern the field of dentistry (as opposed to surgery) is a critical difference between the cited references and the Applicants’ invention. The importance of this critical difference is evident by the unequivocal failure of Mannschedel and Shoher to teach the claimed step of the present invention of sterilizing the thermopolymer composition. Dentistry, by its very nature, involves work in a nonsterile environment (i.e. a patient’s mouth), and as such materials for use in filling dental voids are not (and need not be) provided in a sterile manner. Surgery, on the other hand, involves invasive procedures designed to access areas of the human body that are prone to infection. As such, surgery mandates the sterility of all instruments and implants to be used. Neither Mannschedel

nor Shoher teach sterilization of the thermopolymer because sterilization of dental implants is not necessary.

Until the applicant's invention, gutta percha and compounds and/or mixtures containing gutta percha had never been used in surgical applications. Neither Mannschedel nor Shoher teach the use of gutta percha or any other thermopolymer composition for use in surgery. Therefore, it would not have been obvious for one of ordinary skill in the art relying on Mannschedel and Shoher, alone or in combination, to arrive at the applicant's invention at the time the invention was made.

It appears to the applicant that the examiner, in rejecting the present invention for obviousness, is engaging in impermissible hindsight. "Measuring a claimed invention against the standard established by section 103 requires the oft difficult but critical step of casting the mind back to the time of invention, to consider the thinking of one of ordinary skill in the art, guided only by the prior art references and the then accepted wisdom in the field." *In re Dembiczak*, 175 F.3d 994 (Fed. Cir. 1999). Furthermore, "it is impermissible to use the claimed invention as an instruction manual or 'template' to piece together the teachings of the prior art so that the claimed invention is rendered obvious..." *In re Fritch*, 972 F.2d 1260 (Fed. Cir. 1992).

Both Mannschedel and Shoher teach compositions for use in dentistry, which by its nature involves work in a nonsterile environment. Consequently, there is nothing in either the Mannschedel or Shoher references (alone or in combination) that suggests a step of sterilizing the composition before applying it to a root canal (Mannschedel) or dental cavity (Shoher). Similarly, there is no motivation in either Mannschedel or Shoher, alone or in combination, to use a thermopolymer composition containing gutta percha in surgical applications. Until the applicant's invention, compositions containing gutta percha had never been used in surgery. "The fact that a prior art device could be modified so as to produce the claimed device is not a basis for an obviousness rejection unless the prior art suggested the desirability of such a modification." *In re Gordon*, 733 F.2d 900 (Fed. Cir. 1984). Since sterilization of dental implants is not necessary in such a nonsterile environment, sterilization of a thermopolymer

composition previously used only in dental applications would not have been obvious to one of ordinary skill in the art at the time of the applicant's invention. There is no evidence that gutta percha compounds had been used in surgical applications prior to the applicant's invention, and therefore the use of gutta percha compounds in surgery would not have been obvious to one of ordinary skill in the art at the time the invention was made.

Based on the foregoing, Applicants respectfully submit that the Mannschedel and Shoher references, whether taken alone or in combination, fail to contain the requisite teaching or suggestion that would have lead one of ordinary skill in the art to the present invention as set forth in amended claim 16. Therefore, it is respectfully requested that the rejection in Paragraph 5 of the Office Action be withdrawn. Claim 16 is believed to be in proper condition for allowance and an indication of such is hereby respectfully requested.

Claims 19 & 20, being dependent upon and further limiting independent claim 16, should be allowable for the reasons set forth in support of the allowability of claim 16, as well as the additional limitations they contain.

**B. Mannschedel in view of Shoher and Kosegaki**

Claims 17-18 were rejected by the Examiner under 35 USC 103(a) as being unpatentable over Mannschedel and Shoher et al, in view of US Patent No. 4,569,736 to Kosegaki et al. ("Kosegaki"). Applicants respectfully traverse this rejection as set forth below.

Claims 17 & 18 are dependent upon and further limit claim 16. As discussed above, neither the Mannschedel nor Shoher references, alone or in combination, teach all of the claimed features of independent claim 16. Notably, Mannschedel and Shoher fail to teach the claimed step of sterilization of the thermopolymer composition. Kosegaki does not remedy this void. Kosegaki discloses medical instruments, e.g. syringes, which can be sterilized by gamma irradiation and which are made of polyolefin resins (preferably a polypropylene polymer) which are resistant to gamma irradiation (abstract). Sterilization of medical instruments is commonly known in the art due to the fact that medical instruments are typically reusable, and sterilization

between uses is necessary at the very least to prevent the transfer of disease-causing bacteria from one patient to another. The sterilization of medical instruments as disclosed by Kosegaki would not motivate one of ordinary skill in the art to sterilize a thermopolymer composition for use in dental applications (as taught by Mannschedel).

Based on the foregoing, Applicants respectfully submit that the Mannschedel, Shoher, and Kosegaki references, whether taken alone or in combination, fail to contain the requisite teaching or suggestion that would have lead one of ordinary skill in the art to the present invention as set forth in amended claim 16. It is respectfully requested that the rejection in Paragraph 6 of the Office Action be withdrawn. Claim 16 is believed to be in proper condition for allowance and an indication of such is hereby respectfully requested.

Claims 17 & 18, being dependent upon and further limiting independent claim 16, should be allowable for the reasons set forth in support of the allowability of claim 16, as well as the additional limitations they contain.

### **III. New Claims**

New claims 21-26 have been added to further limit the method of preparing a thermopolymer composition for use in surgery described in claim 16. New claims 27-32 have been added to claim a method for providing a thermopolymer composition for use in surgery. No new matter has been entered. Since claims 21-26 are ultimately dependent upon independent claim 16, and the methods claimed in claims 27-38 are not taught in the prior art, the Applicants believe that the new claims are in condition for allowance based on the reasoning presented above, and respectfully request a favorable indication in that regard.

### CONCLUSION

The foregoing amendment has been submitted to place the present application in condition for allowance. Favorable consideration and allowance of the claims in this application is respectfully requested. In the event that there are any questions concerning this Amendment or the application in general, the Examiner is cordially invited to telephone the undersigned attorney so that prosecution may be expedited.

Respectfully submitted,  
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